

REMARKS

Claims 1-7, 14-21, 29-45 and 54-59 are pending for examination with claims 1, 29, 37 and 54 being independent claims. Claims 8-13 have been withdrawn. No new matter has been added.

Applicants acknowledge the courtesies extended by Examiner Matthews during a telephone interview with the undersigned attorney on September 21, 2006. The substance of the interview is summarized in the remarks set forth below.

Allowable Subject Matter

Applicants acknowledge the Examiner's indication that claims 37-45 are allowed and that claims 4, 33 and 57 recite allowable subject matter. Claims 4, 33 and 57 have not been rewritten at this time as they depend from claims believed to be allowable for reasons set forth below.

Rejections Under 35 U.S.C. §102Claims 1-3, 5-7, 14-17, 20, 29-32, 34, 35, 54-56 and 58

Claims 1-3, 5-7, 14-17, 20, 29-32, 34, 35, 54-56 and 58 stand rejected under 35 U.S.C. §102(b) as purportedly being anticipated by Meier (U.S. Patent No. 3,416,524). Applicants respectfully traverse these rejections for reasons similar to those set forth in previous responses concerning prior rejections in view of Mulhauser (U.S. Patent No. 5,766,246).

Independent claims 1, 29 and 54 are each directed to an implantable prosthesis including, *inter alia*, a layer of repair fabric and a barrier layer configured to inhibit the formation of adhesions between at least a portion of a surface of the repair fabric and adjacent tissue and organs. The layer of repair fabric has an outer peripheral edge or an outer margin with an outer peripheral edge.

Claim 1 recites that the prosthesis also includes a peripheral barrier that inhibits the formation of adhesions with adjacent tissue and organs thereto.

Claims 29 and 54 recite that the entire thickness of the outer peripheral edge is adapted to inhibit the formation of adhesions thereto.

Meier is directed to a non-adherent surgical dressing including a laminated pad 13 with a cellulosic layer 14 and a resin fiber layer 15 which are joined by needled resin fibers 16 using a needling and heat fusion process. The cellulosic layer has moisture absorption properties while

the resin fiber layer has a porous surface which serves as the non-adherent contact surface for the wound and which permits free flow to moisture. The pad is surrounded by an edge frame or crown 12 which stabilizes the edges of the cellulosic layer and the resin fiber layer.

In the Office Action, the Examiner contends that the peripheral edge of the repair fabric is adapted to inhibit the formation of adhesions by peripheral barrier 12. (Office Action, page 2). During the interview, the Examiner indicated that the Meier frame 12 inhibits adhesions to the edge of the fabric because it will essentially block adhesions directly to the fabric. As discussed during the interview, one of ordinary skill in the art, when considering the teachings of the present specification, would understand that the claimed peripheral barrier, such as recited in claim 1, inhibits adhesions to itself. Nevertheless, to clarify this aspect of the claim, Applicants have amended claim 1 to recite that the peripheral barrier inhibits the formation of adhesions with adjacent tissue and organs *thereto*.

As discussed during the interview, Meier does not teach or suggest that the frame has any type of adhesion inhibiting properties. Rather, Meier discloses that the frame provides freedom from fraying, loose fibers, delamination and the like by surrounding and stabilizing the edges of the cellulosic layer and the resin fiber layer. (Col. 2, lines 51-56). Meier indicates that the frame may be fabricated from any of a variety of materials, such as an inert thermoplastic substance, which is sufficiently flexible for purposes of being applied with the pad to curved body surfaces and yet which affords sufficient rigidity to stabilize the pad and prevent delamination, etc. (Col. 2, line 67 to Col. 3, line 2).

As explained during the interview and in prior responses in connection with Mulhauser, which similarly employs a semi-rigid frame or ring for maintaining the prosthesis in a predetermined shape, the adhesion resistant properties of a soft tissue repair prosthesis are affected by various factors including the surface texture and pore size of the material that forms the prosthesis or portions of the prosthesis. (See Eldridge Declaration, paragraph 9). Thus, a prosthesis may be either resistant to the formation of adhesions or promote tissue ingrowth and adhesions depending upon the particular structural characteristics of its material. (See Eldridge Declaration, paragraph 9). For example, a prosthetic material having a surface texture or porosity of approximately 10 μ m or more is susceptible to adhesions with tissue or muscle. (See Eldridge Declaration, paragraph 9).

As discussed during the interview, Meier provides no teaching or suggestion as to any structural characteristics of the frame that would allow one of ordinary skill in the art to determine its adhesion resistant properties. Although Meier discloses that the frame may be formed from any of various materials, Meier is silent as to the surface texture and porosity of the frame, such that one of ordinary skill in the art would not consider the Meier frame as necessarily being resistant to tissue ingrowth and adhesions to tissue and muscle. Thus, Meier does not disclose either a peripheral barrier that inhibits the formation of adhesions with tissue and organs thereto, as recited in claim 1, or an outer peripheral edge that is adapted to inhibit the formation of adhesions thereto, as recited in claims 29 and 54.

In view of the foregoing, claims 1, 29 and 54 patentably distinguish over Meier, such that the rejections under §102 should be withdrawn.

Claims 2-3, 57, 14-17 and 20, claims 30-32, 34 and 35, and claims 55-56 and 58 respectively depend from claims 1, 29 and 54 and are patentable for at least the same reasons.

Claims 1, 2, 14, 15 and 20

Claims 1, 2, 14, 15 and 20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Ory (U.S. Patent No. 6,264,702). Applicants respectfully traverse these rejections.

As indicated above, claim 1 recites that the prosthesis includes, *inter alia*, a peripheral barrier that inhibits the formation of adhesions with adjacent tissue and organs thereto. Claim 1 further recites, *inter alia*, that the peripheral barrier extends across the entire thickness of a portion of the outer peripheral edge of the fabric.

Ory discloses an implantable prosthesis including a layer of repair fabric 4 and a barrier layer 3. Ory indicates that the barrier layer projects beyond the fabric layer in such a way as to protect the prosthesis from visceral contacts. (Col. 4, lines 26-30).

As discussed during the interview, Ory does not teach or suggest a peripheral barrier that extends across the entire thickness of the outer peripheral edge of the fabric. More particularly, although the barrier layer of the Ory prosthesis projects beyond the repair fabric, there is no teaching or suggestion that the layer extends across any portion of the fabric edge, let alone its entire thickness. However, the Examiner asserted that, since Ory discloses the barrier layer being flexible, the portion projecting beyond the fabric is capable of being folded across the fabric edge.

As the Examiner is aware, a claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. See MPEP 2131. Applicants respectfully submit that, even assuming for the sake of argument only that the barrier layer is capable of being folded across the fabric edge, Ory still fails to disclose a configuration of the prosthesis in which the barrier layer actually does extend across the entire thickness of the edge. Because Ory does not disclose the claimed structure, claim 1 is not anticipated by Ory such that the rejection of claim 1 under §102 is improper and should be withdrawn.

Notwithstanding the foregoing, in an effort to advance prosecution of this application, claim 1 has been amended to recite that the peripheral barrier extends about at least a portion of the outer peripheral edge of the layer of repair fabric and is maintained across the entire thickness of the portion of the outer peripheral edge. As discussed during the interview, even if the Ory barrier layer could be folded across the fabric edge, Ory does not teach or suggest a prosthesis with a peripheral barrier that is maintained across the entire thickness of a portion of the peripheral edge of the fabric layer. Accordingly, claim 1 patentably distinguishes over Ory for at least this additional reason.

Claims 2, 14, 15 and 20 depend from claim 1 and are patentable for at least the same reasons set forth above.

Rejections Under 35 U.S.C. §103

Claims 16-19 and 21

Claims 16-19 and 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ory in view of Scharber (US 6,075,180).

Without acceding to the propriety of the reference combination suggested by the Examiner, claims 16-19 and 21 depend from claim 1 and are patentable for at least the same reasons set forth above. Accordingly, the rejection of claims 16-19 and 21 under §103 should be withdrawn.

Claims 21, 36 and 59

Claims 21, 36 and 59 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Meier in view of Eldridge (WO 98/49967).

Without acceding to the propriety of the reference combination suggested by the Examiner, claims 21, 36 and 59 depend from claims 1, 29 and 54, respectively, and are patentable for at least the same reasons set forth above. Accordingly, the rejection of claims 21, 36 and 59 under §103 should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the undersigned at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

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Docket No.: D0188.70125US00

Date: October 3, 2006

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